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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/336,091	06/18/1999	JACQUES VAN SNICK	L0461/7063-J	7247

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EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/336,091	VAN SNICK ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,5,7,9,14,76-79 and 81-87* is/are pending in the application.

4a) Of the above claim(s) *84-87* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,5,7,9,14,76-79,81-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Applicant's election of the species compositions containing MAGE-AI HLA DRB1* 15 binding peptides and MAGE-AI HLA class I binding peptides in the paper received 1/20/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 84-87 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the paper received 1/20/2004.

3. Claims 2,5,7,9,14,76-79,81-83 are under consideration.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 5,14,78,83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the claimed inventions. Claims 2 and 9 (from which the rejected claims depend) recite a HLA DRB1*15 binding peptide that consists of SEQ. ID. NO:7 with 0-11 amino acids added at either or both ends. Therefore, claims 5,14,78,83 encompass use of a endosomal targeting peptide of 2-11 amino acids because the endosomal targeting peptide would only be attached to one end of the HLA DRB1*15 binding peptide and the endosomal targeting peptide attached to SEQ. ID. NO:7 can be only 2-11 amino acids. There is no disclosure in the specification as originally filed of use of an endosomal targeting peptide of 2-11 amino acids in length or use of such a peptide derived from the peptides of claims 78,83. There is no written description of the scope of the claimed inventions in the specification as originally filed (eg. the claimed inventions constitute new matter).

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 2,9,81 are rejected under 35 U.S.C. 102(b) as being anticipated by Fikes et al. (WO 95/04542).

Fikes et al. teach a peptide that contains all of the amino acids of SEQ. ID. No. 7 except the first and last amino acids (see claim 4, Seq. Id. No. 15). Said peptide is derived from MAGE A1 (alias MAGE 1). Claims 2,9,81 encompass a peptide that has one amino acid deleted from SEQ. ID. No. 7. Fikes et al. teach that the amino acid residue Glu can be added at the N-terminus of said peptide (see page 10, last paragraph). This would yield the peptide of claim 2,9,81 wherein said peptide would bind HLA DRB*15 because it is the peptide recited in the claim. Fikes et al. teach MAGE 1 peptide compositions containing a MAGE 1 class binding peptide and a MAGE 1 class II binding peptide (see page 12, last paragraph) . In the instant rejection, the MAGE 1 class I binding peptide would function to bind HLA DRB1*15 (because it has the sequence recited in the claim) whilst the T helper epitope disclosed in page 12, last paragraph would bind MHC class I. There are hundreds of different MHC class I alleles that would bind largely discrete and nonoverlapping subsets of MAGE 1 derived peptides, wherein it would be reasonable to conclude that at least a fraction of said alleles could bind a T helper MAGE 1 epitope as per disclosed in page 12, last paragraph.

Regarding applicants comments, Fikes et al. teach a peptide that contains all of the amino acids of SEQ. ID. No. 7 except the first and last amino acids (see claim 4, Seq. Id. No. 15). Said peptide is derived from MAGE A1 (alias MAGE 1). Claims 2,9 encompass a peptide that has one amino acid deleted from SEQ. ID. No. 7. Fikes et al. teach that the amino acid residue Glu can be added at the N-terminus of said peptide (see page 10, last paragraph).

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 2,7,9,79,81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fikes et al. (WO 95/04542) in view of Gelder et al. (US Patent 6,043,347).

Fikes et al. teach a peptide that contains all of the amino acids of SEQ. ID. No. 7 except the first and last amino acids (see claim 4, Seq. Id. No. 15). Said peptide is derived from MAGE A1 (alias MAGE 1). Claims 2,9,81 encompass a peptide that has one amino acid deleted from SEQ. ID. No. 7. Fikes et al. teach that the amino acid residue Glu can be added at the N-terminus of said peptide (see page 10, last paragraph). This would yield the peptide of claim 2, wherein said peptide would bind HLA DRB*15 because it is the peptide recited in the claim. Fikes et al. teach MAGE 1 peptide compositions containing a MAGE 1 class binding peptide and a MAGE 1 class II binding peptide (see page 12, last paragraph) . Fikes et al. do not teach a peptide containing D-amino acids. Gelder et al. teach modified peptides containing D-amino acids (see column 20) and that such peptides have increased stability (see column 20). Said peptides would also be non-hydrolyzable because D-amino acid modified peptides have this property (eg. see claim 7 upon which claim 79 depends). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Fikes et al. teach the claimed peptide except for D-amino acid modification, while Gelder et al. teach modified peptides containing D-amino acids (see column 20) and that such peptides exhibit increased stability. One of ordinary skill in the art would have been motivate to do the aforementioned because Gelder et al. that teach modified peptides containing D-amino acids have increased stability.

10. Claims 2,9,76,77,81,82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fikes et al. (WO 95/04542).

In the instant rejection, the claims are addressed as encompassing a peptide consisting of SEQ. ID. No.7. Fikes et al. teach a peptide that contains all of the amino

acids of SEQ. ID. No. 7 except the first and last amino acids (see claim 4, Seq. Id. No. 15). Said peptide is derived from MAGE A1 (alias MAGE 1). Fikes et al. do not teach that the peptide contains all of the amino acids of SEQ. ID. No. 7. Fikes et al. teach that the peptide can be optionally flanked by additional MAGE 1 amino acids (see page 5, penultimate paragraph). Fikes et al. teach that the peptides are less than 15 amino acids (see page 5, last paragraph). Fikes et al. teach that the peptides are about 11 residues, which would encompass a 12mer peptide (see page 5, last paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Fikes et al. teach a Mage 1 peptide that contains all of the amino acids of SEQ. ID. No. 7 except the first and last amino acids , that the peptide can be optionally flanked by additional MAGE 1 amino acids, and that the peptides are less than 15 amino and are about 11 residues, which would encompass a 12mer peptide (see page 5, last paragraph). One of ordinary skill in the art would have been motivated to do the aforementioned because Fikes et al. teach that the peptides of their invention peptides are less than about 15 residues in length and usually contain about 11 residues, which would encompass a 12mer peptide. Fikes et al. teach MAGE 1 peptide compositions containing a MAGE 1 class binding peptide and a MAGE 1 class II binding peptide (see page 12, last paragraph) .

11. Claims 7,79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fikes et al. as applied to claims 2,9,76,77,81,82 above, and further in view of Gelder et al. (US Patent 6,043,347).

The previous rejection renders obvious the claimed invention except for a peptide containing D-amino acids. Gelder et al. teach modified peptides containing D-amino acids (see column 20) and that such peptides have increased stability (see column 20). Said peptides would also be non-hydrolyzable because D-amino acid modified peptides have this property (eg. see claim 7 upon which claim 79 depends). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Fikes et al. teach the claimed peptide except for D-amino acid modification, while Gelder et al. teach modified peptides containing D-amino acids (see column 20) and that such peptides exhibit increased stability. One of ordinary skill in the art would have been motivate to do the

aforementioned because Gelder et al. that teach modified peptides containing D-amino acids have increased stability.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 2720841,. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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